I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV324845787US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 6-7-04 Signature: Maura Gallagher
(Maura Gallagher)

Docket No.: SUPP-P01-016
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Brazelton et al

Application No.: 09/993,045 Group Art Unit: 1632

Filed: November 13, 2001 Examiner: Q. Janice Li

For: Methods for Treating Disorders of Neuronal Deficiency with Bone Marrow Derived Cells

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 35 U.S.C. §1.132 OF TIMOTHY BRAZELTON

Sir:

Timothy Brazelton, Ph.D., hereby declares and states as follows:

1. I am a named inventor of the above-identified patent application, and of the subject matter described and claimed therein.

2. I am presently a Research Scientist at the Baxter Laboratory for Genetic Pharmacology, Stanford, CA. I conducted my doctoral research in the laboratory of Dr. Helen Blau at the

Stanford University Medical School. My curriculum vitae is attached to this Declaration as Exhibit BA.

3. Since the filing of the above-mentioned patent applications, additional data has been generated in Dr. Blau's laboratory that demonstrate the effectiveness of the techniques disclosed in the patent application. These data demonstrate that bone marrow derived cells, administered intravenously, ameliorate symptoms of Parkinson's disease in a well-established mouse model. The methods used and the data generated are described below.

4. We used a mouse model of Parkinson's disease. Parkinson's disease (PD) is a common neurodegenerative disorder characterized clinically by tremor, slowness of movement, stiffness, and postural instability. These clinical features are primarily attributable to the degeneration of nigrostriatal dopaminergic neurons in the substantia nigra (SN), loss of their projecting nerve fibers to the striatum, and depletion of the neurotransmitter dopamine. The neurotoxin MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine) produces neurochemical and behavior deficits in when administered to mice, monkeys, and humans. MPTP-induced Parkinson's in mice is considered an excellent model of PD, one of few models for PD where the causative agent is known to induce similar Parkinsonian symptoms in humans and animals.

5. Bone marrow derived cells were prepared and administered as described below. Bone marrow was harvested from 8-10 week old, male transgenic mice that ubiquitously expressed an enhanced version of green fluorescent protein (GFP) driven with a B-actin promoter and a CMV enhancer. Briefly, donor mice were euthanized by cervical dislocation, immersed in 70% ethanol, and the skin was peeled back from a midline, circumferential incision. Large limb bones (femur, tibia, & humerus) were surgically isolated and placed in ice-cold of calcium and magnesium-free, Hank's balanced salt solution (HBSS, Irvine Scientific) with 2% FBS for up to 90 minutes. In a tissue culture hood, the tips of the bones were removed and a 25 gauge needle containing 1 mL of ice-cold HBSS with 2% FCS was inserted into the marrow cavity and used to wash the marrow out into a sterile culture dish. Marrow fragments were dissociated by titurating through the 25 gauge needle and the resulting suspension was filtered through sterile 70 μm nitex mesh. The filtrate was cooled on ice, spun for 5 minutes at 250 x g, and the pellet was resuspended in ice-cold HBSS with 2% FCS to $8x10^6$ nucleated cells per mL. Simultaneously,

the marrow of 8-10 week old, isogeneic (C57B/6, Jackson Laboratories, USA), recipient mice was ablated by lethal irradiation (two doses of 475 cGy, three hours apart). Within the 2 hours following lethal irradiation, each mouse received 125μL of the unfractionated BM suspension by tail vein injection.

6. MPTP (Sigma, USA) was administered in four intraperitoneal injections of 20mg/kg (free base) at 3 hour intervals for a total dose of 80 mg/kg. This dose was sufficient to induce biochemical and behavioral deficits along with dopaminergic cell loss.

7. Bone marrow transplantation (BMT) into recipient mice either before and after MPTP-induced neurodegeneration increased the number of tyrosine hydroxylase dopaminergic neurons in the substantia nigra and significantly increased dopamine transporter immunoreactivity in the striatum compared to non-transplanted, MPTP-treated mice. Importantly, there was significantly improved motor performance of the BM-transplanted, MPTP-injured mice as determined by rotorod and open field behavior tests. For the learned, accelerating rotorod test, mice are trained prior to the experiment to stay on a rotating rod that accelerates over time. For each rotorod test, mice are tested 3 times and the length of time on the rod is recorded.

8. Fig. 1, shown in Exhibit BB, illustrates the rotorod performance of three groups of mice. On day 0, mice received an injection of either MPTP or saline. The first rotorod test occurred on day 2. On day 6, one group of MPTP-treated mice were lethally irradiated and then received a whole bone marrow by tail vein injection. Mice were then tested on the rotorod on days 8, 15 and 20. The group of mice that received a BMT had a steady improvement in their rotorod performance in the 2 weeks following the BMT while the non-transplanted group's poor performance was maintained. Data is representative of 2 experiments. Saline group: n=10, BMT/MPTP: n=10, and MPTP: n=7. Data represents the mean time±SEM spent on the rotorod prior to falling. Student t tests for MPTP vs MPTP/BMT are p=0.03 and p=.0004 at days 15 and 20, respectively.

9. In an additional experiment, lethally irradiated mice received a transplant of whole bone marrow 8 weeks prior to MPTP-induced injury (Fig. 2, in Exhibit BB). Additional control groups included a group that received a BMT but no MPTP injection (BMT/saline) and a group that received head irradiation and MPTP injection to ensure that irradiation wasn't inhibiting the

response of cells in the CNS to the MPTP injection (Head irr/MPTP). While the BMT-transplanted group did demonstrate an acute loss of motor function in response to MPTP injection similar to that of non-transplanted mice (MPTP group), the BMT mice rapidly recovered and maintained their lost motor function. Figure 2 is representative of 3 experiments (n=7 for each group). The student t tests for the MPTP vs the BMT/MPTP groups are p=.02, p=.04, and p<0.0001 at days 8, 15, and 20, respectively.

10. BMT, therefore, improved both the pathological and functional measures of Parkinson's disease in this murine model and indicate that BMT can be used as a novel non-invasive, cell-based therapy for Parkinson's disease. These data demonstrate that the administration of bone marrow derived cells is effective to ameliorate symptoms of a neurodegenerative disease in a well-established animal model.

11. I further state that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7-June-2004 Signed: Unexecuted

Dr. Timothy Brazelton

Exhibit BA

CURRICULUM VITAE OF DECLARANT TIMOTHY BRAZELTON, PH.D.

Application No. 09/993,045, filed 13-Nov-2001
Inventor: Brazelton et al.
Title: Methods for Treating Disorders of Neuronal Deficiency with Bone Marrow Derived Cells

Examiner: Q. Janice Li
Art Unit: 1632

CURRICULUM VITAE

TIMOTHY R. BRAZELTON, Ph.D.

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brazelt@stanford.edu

EDUCATION

Undergraduate

Saint Olaf College
Northfield, Minnesota
B.A. 1991
Majors: Biology, Chemistry

Graduate

Stanford University School of Medicine
Stanford, California
M.D. 2004 (expected)
Ph.D. 2002 (Plasticity of adult bone marrow cells)

PROFESSIONAL EXPERIENCE

2002-present — Research scientist, Baxter Laboratory for Genetic Pharmacology, Stanford, CA.

2000-present — Editor of Stem Cell Biology, *The Journal of Regenerative Medicine*

1998-2002 — Graduate student, Dept. Molecular Pharmacology, Stanford, CA. Explored ability of adult bone marrow cells to generate diverse cell types in vivo including neurons, skeletal muscle, fibroblasts, smooth muscle cells, and various types of epithelium. Myoblast-mediated in vivo delivery of growth factors for tissue regeneration.

1996-2001 — Founder & Director, *The International Lung Transplant Database*, Stanford, CA Founded and directed the largest database of detailed lung transplant information in the world. Involves several academic centers from the U.S, Europe, and Australia. Wrote customized software which uses patient data to model and compare outcomes between competing clinical trial designs.

PROFESSIONAL EXPERIENCE (continued)

1996-1997	Director, Phase I FDA trials for SDZ-RAD, Stanford, CA. Evaluated safety and pharmacokinetics of SDZ-RAD (a rapamycin derivative) in lung transplant recipients with and without cystic fibrosis.
1994-1997	Medical student researcher, Laboratory for Transplant Immunology, Stanford, CA. Developed and tested novel hypotheses regarding the etiology of chronic vascular and airway rejection. Explored mechanisms of action and efficacy in rodents of leflunomide as well as other novel immunosuppressive compounds.
1991-1992	Research assistant, Atmospheric Scientific Research Station, Whiteface Mountain, NY
1991	Field study supervisor, British Fisheries Service, Turks & Caicos Islands Settlement patterns of *Panulirus argus* on South Caicos,

AWARDS, INVITED PLENARY TALKS, AND PROFESSIONAL SOCIETIES

2003	Invited talk, American Association of Blood Banks Annual Meeting, San Diego, CA
2003	Invited talk, 3nd Annual Conference on Mesenchymal and Nonhematopoietic Stem Cells, New Orleans
2003	Invited plenary talk, American Society for Blood and Marrow Transplantation and the International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry Tandem BMT Meeting, Keystone, CO
2002	Invited talk, 2nd Annual Conference on Mesenchymal and Nonhematopoietic Stem Cells, New Orleans
2002	Invited plenary talk, Stem Cells & Regenerative Medicine Conference, San Diego
2002	Invited talk, European Society of Cardiology, Berlin
2001	Invited plenary talk, The 7th Basic Sciences Symposium of the Transplantation Society, Bern, Switzerland
2000	Honorary Member, Society of Regenerative Medicine
1998	National Institute of Health, Five year Ph.D. training grant, Stanford University School of Medicine
1998	Award for Clinical Research, Western Section of the American Federation for Clinical Research, Carmel, CA.

For abstract entitled " CREATION OF A MULTINATIONAL RESEARCH DATABASE WITH INTERNET-BASED DATA COLLECTION AND MANAGEMENT, CLINICAL PREDICTION SOFTWARE, AND REMOTE ANALYSIS: A MEANS TO ACCELERATE THE DRUG DEVELOPMENT PROCESS"

1998 Best Clinical Trial Management of 1997, Novartis Pharmaceuticals

For phase I FDA trial of SDZ-RAD, Stanford Medical School

1998 Caves Award Presentation, International Society of Heart and Lung Transplantation, Chicago.

For abstract entitled " RECIPIENT MESENCHYMAL CELLS INFILTRATE AND REMODEL MEDIAL AND ADVENTITIAL TISSUE IN THE RAT FEMORAL ARTERY ALLOGRAFT MODEL OF CHRONIC VASCULAR REJECTION"

AWARDS AND PROFESSIONAL SOCIETIES (continued)

1998 Plenary Talk, International Society of Heart and Lung Transplantation, Chicago.

1998 Van Arman Award, 9th International Conference of the Inflammation Research Association, Hershey, PA.

For abstract and paper entitled "CHRONIC REJECTION: THE RESULT OF UNCONTROLLED REMODELING OF GRAFT TISSUE BY RECIPIENT MESENCHYMAL CELLS?"

1998 Member, American Society of Transplantation

1998 Member, The Transplantation Society

1998 Member, The International Society for Heart & Lung Transplantation

1997 Award for Research in Clinical Pharmacology, Western Section of the American Federation for Clinical Research, Carmel, CA, Tied for first place.

For abstract entitled "ASSESSMENT OF DHODH ACTIVITY IN WHOLE BLOOD: A POTENTIAL PHARMACODYNAMIC ASSAY TO MONITOR LEFLUNOMIDE"

1997 Caves Award Presentation, International Society of Heart and Lung Transplantation, London.

For abstract entitled "EFFICACY OF IMMUNOSUPPRESSIVE AGENTS CORRESPONDS TO THEIR ABILITY TO MAINTAIN DONOR TISSUE PHENOTYPE IN ALLOGRAFTED TRACHEAS"

1997 Plenary Talk, International Society of Heart and Lung Transplantation, London.

1997 Keynote speaker - Novartis International Workshop on Lung Transplantation Clinical Trial Design, Basel, Switzerland.

1997 Lutheran Brotherhood, Five year MD/PhD scholarship, Stanford Medical School

1996 Van Arman Award, 8th International Conference of the Inflammation Research Association, Hershey, PA, First place.

For abstract and paper entitled "REMOVAL OF ALLOIMMUNE INJURY FAILS TO PREVENT SUBSEQUENT PROGRESSION OF OBLITERATIVE AIRWAY DISEASE IN RAT TRACHEAL ALLOGRAFTS"

1995 Member, American Association for the Advancement of Science

1995 Member, American Medical Association

1995 Stanford Medical Scholars, Student Research Award

PUBLICATIONS

1. Brazelton, T., N. Quinn. An ecological survey of settlement sites for juvenile *Panulirus argus* on the North and West Banks of South Caicos, Turks and Caicos Islands. *J. British Fisheries Service*,1991.

2. Reichenspurner, H. B. Adams, V. Soni, T.R. Brazelton, R. Shorthouse, B. A. Reitz, G. J. Berry, R. E. Morris. Obliterative Airway Disease After Heterotopic Tracheal Xenotransplantation in a Concordant Rodent Model: Pathogenesis and Treatment. *Transplantation Proceedings*, 28(2): 729-30, 1996.

3. Brazelton, T.R., and Morris, R. E. Molecular Mechanisms of action of new xenobiotic immunosuppressive drugs: tacrolimus, sirolimus, mycophenolate mofetil, and leflunomide. *Current Opinion in Immunology*, 8:(5) 710-20, 1996.

4. Brazelton, T.R., Cheung, A. C. Morris, R. E. "Pharmacologic Immunosuppressants in Xenografting" in *Xenografting*, edit. J. C Cooper, 1996.

5. Nair, R.V., X. Huang, R. Shorthouse, B. Adams, T. R. Brazelton, R. Braun-Dullaeus, R.E. Morris. Antiproliferative effects of rapamycin on growth-factor stimulated human adult lung fibroblasts in vitro may explain its superior efficacy for prevention and treatment of allograft obliterative airway disease in vivo. *Transplantation Proceedings* 29(1-2):614-5, 1997.

6. Cheung, A., M. Billingham, T. R. Brazelton, B. Zheng, H. Silva, R. Shorthouse, R. E. Morris. Leflunomide abrogates hyperacute rejection in presensitized rats. *Transplantation Proceedings*, 1997 Feb-Mar, 29(1-2):1294-5

7. Brazelton, T. R., B. A. Adams, A. C. Cheung, R. E. Morris. Progression of obliterative airway disease occurs despite the removal of immune reactivity by retransplantation. *Transplantation Proceedings*, 1997 Sep, 29(6): 2613.

8. Brazelton, T. R. , R. Shorthouse, X. Huang, R.E. Morris. Infiltrating recipient mesenchymal cells form the obliterative airway disease lesion and dramatically

remodel graft tissue in a model of chronic lung rejection. *Transplantation Proceedings*, 1997 Sep, 29(6): 2614.

9. Reichenspurner, H., V. Soni, M. Nitschke, G. J. Berry, T.R. Brazelton, R. Shorthouse, X. Huang, B. A. Reitz, R. E. Morris. Obliterative airway disease after heterotopic tracheal xenotransplantation. Pathogenesis and prevention using new immunosuppressive agents. *Transplantation* 64(3):373-383, 1997.

10. Reichenspurner, H., V. Soni, M. Nitschke, G.J. Berry, T.R. Brazelton, R. Shorthouse, X. Huang, J. Boname, R. Girgis, B.A. Reitz BA, R.E. Morris. Enhancement of obliterative airway disease in rat tracheal allografts infected with recombinant rat cytomegalovirus. *Journal of Heart and Lung Transplantation*, 1998 May, 17(5):439-51.

11. Segarra, T.R. Brazelton, N. Guterman, B. Hausen, W. Jacobsen, R.E. Morris, L.Z. Benet, U. Christians. Development of a high-performance liquid chromatographic-electrospray mass spectrometric assay for the specific and sensitive quantification of the novel immunosuppressive macrolide 40-*O*-(2-hydroxyethyl) rapamycin. *Journal of Chromatography* B 720: 179-187, 1998.

12. Brazelton, T.R., B. Adams, R. Shorthouse, and R.E. Morris. Chronic rejection: The result of uncontrolled remodeling of graft tissue by recipient mesenchymal cells? Data from two rodent models and the effects of immunosuppressive therapies. *Inflammation Research*, 48(suppl 2):S-1-S2, 1999.

13. Adams, B.A., T.R. Brazelton, G.J. Berry, R.E. Morris. The role of respiratory epithelium in a rat model of obliterative airway disease. *Transplantation*, 69(4):661-4, 2000.

14. Adams B.F., G.J. Berry, X. Huang,R. Shorthouse, T.R. Brazelton, Morris RE.. Immunosuppressive therapies for the prevention and treatment of obliterative airway disease in heterotopic rat trachea allografts. *Transplantation*, 69(11):2260-6, 2000.

15. Ikonen, T.S., T. R. Brazelton, G. J. Berry, R.S. Shorthouse, R.E. Morris. Epithelial re-growth is associated with inhibition of obliterative airway disease in orthotopic tracheal allografts in non-immunosuppressed rats. *Transplantation*, 70(6):857-63, 2000.

16. Brazelton, T.R., F.V.M. Rossi, G. Keshet, H.M. Blau. From bone marrow to brain: Adult bone marrow-derived cells give rise to neuronal phenotypes in mice. *Science*, 290:1775-9, 2000.)

17. Doyle, R.L., M.I. Hertz, J.M. Dunitz, J.E. Loyd, A.A. Stecenko, R.L. Wong, K.A. Chappell, T.R. Brazelton, J.M. Kovarik, S. Appeldingemanse, L. Dou, H.T. Smith, D. Tudor, R.E. Morris. RAD in stable lung and heart/lung transplant recipients: safety,

tolerability, pharmacokinetics, and impact of cystic fibrosis. *Journal of Heart and Lung Transplantation*, 20:330-9, 2001.

18. Brazelton, T.R., Springer M.L., H.M Blau. Not the usual suspects: the unexpected sources of tissue regeneration. *Journal of Clinical Investigation*, 107:1355-6, 2001.

19. Morikawa, M., T.R. Brazelton, G.J. Berry, R.E. Morris. Prolonged inhibition of obliterative airway disease in murine tracheal allografts by brief treatment with anti-LFA-1 (CD11a) monoclonal antibody. *Transplantation*,71:1616-21, 2001.

20. Blau, H.M., T.R. Brazelton, J.M. Weimann. The evolving concept of a stem cell: Entity or function? *Cell*, 105:829-41, 2001.

21. Blau, H.M., T.R. Brazelton, G. Keshet, F. Rossi. Something in the eye of the beholder. *Science*, 298:361-2, 2002.

22. Weimann, J.M., C.A. Charlton, T.R. Brazelton, R.C. Hackman, H.M. Blau. Contribution of transplanted bone marrow cells to purkinje neurons in human adult brains. *Proceedings of the National Academy of Sciences*, 100(4):2088-2093, 2003.

23. Springer, M.L., C.R. Ozawa, A. Banfi, P.E. Kraft, T.K. Ip, T.R. Brazelton, H.M. Blau. Localized arteriole formation directly adjacent to the site of VEGF-induced angiogenesis in muscle. *Molecular Therapy*, 7(4): 441-449, 2003.

24. Singer, L.G., T.R. Brazelton, R.L. Doyle, R.E. Morris, J. Theodore, for the International Lung Transplant Database Study Group. Weight gain following lung transplantation. *Journal of Heart and Lung Transplantation*, 22(8):894-902, 2003.

25. Brazelton, T.R., M. Nystrom, H.M. Blau. Significant differences among skeletal muscles in the incorporation of bone marrow-derived cells. *Developmental Biology*, 262(1):64-74, 2003.

26. Corbel, S.Y., A. Lee, L. Yi, J. Duenas, T.R. Brazelton, H.M. Blau, F.M.V. Rossi. Contribution of hematopoietic stem cells to skeletal muscle. *Nature Medicine, 9:1528-32, 2003.*

27. Briffa N.P., R. Shorthouse, J. Chan, H. Silva, M. Billingham, T. Brazelton, R.E. Morris. Histological and immunological characteristics of, and the effect of immunosuppressive treatment on, xenograft vasculopathy. *Xenotransplantation*, 11(2):149-59: 2004.

28. Ikonen, T., T. R. Brazelton, R. Shorthouse, N. Briffa, G.J. Berry, R.E. Morris. Epithelial regrowth inhibits obliterative airway disease in acutely rejected heterotopic tracheal allografts in non-immunosuppressed rats. (submitted, *Journal of Clinical Investigation*)

29. Nitschke, M., H. Reichenspurner, T. R. Brazelton, B. Adams, R. Shorthouse, G. Berry, E. Mocarski, R. E. Morris. Prevention and treatment of rat-cytomegalovirus infection and its influence on development of obliterative airway disease in rat tracheal allografts using HPMPC: A new antiviral analog. (submitted, *International Journal of Heart and Lung Transplantation*).

30. Singer, L.G., T.R. Brazelton, R.E. Morris, R.L. Doyle, J. Theodore. Cytomegalovirus Infection and Idiopathic Pulmonary Fibrosis. (submitted, *CHEST*).

31. Brazelton, T. R., R.L. Doyle, C. Poirier, R.L. Wong, R.D. Newmark, T. Lin, B.A. Reitz, J. Theodore, R.E. Morris. Risks for BOS1 and Obliterative Bronchiolitis: Multivarariate Regression Analysis of 826 Transplants from 12 centers in the U.S., Europe and Australia. (in preparation)

COMMISSIONED REPORTS

1. T.R. Brazelton, C. Bush, R.D. Newmark, R.L. Wong, R.E. Morris. Outcome estimates from proposed RADB 159 protocols with a patients being enrolled at the time of qualification. December, 1997.

2. T.R. Brazelton, C. Bush, R.D. Newmark, R.L. Wong, R.E. Morris. Outcome estimates from proposed RADB 159 protocols using existing patient data from the U.S., Europe, and Australia. December, 1997.

3. T.R. Brazelton, R.L. Doyle, C. Poirier, R.L. Wong, R.D. Newmark, T. Lin, B.A. Reitz, J. Theodore, R.E. Morris and the Stanford Lung Database Group, the International Lung Transplant Study Group#, and Novartis Pharmaceuticals. The International Lung Transplant Database: White Paper. February, 1998.
   # Alfred Hospital, Victoria, Australia
   Cedars-Sinai Medical Center, Los Angeles, CA, USA
   Cleveland Clinic, OH, USA
   College of Physicians and Surgeons of Columbia University, NY, USA
   Duke University Medical Center, Durham, NC, USA
   Hannover Medical School, Germany
   Loyola University Medical Center, Chicago, IL, USA
   Papworth Hospital, Cambridge, UK
   University of Pittsburgh Medical Center, PA, USA
   Saint Vincent's Hospital, Darlinghurst, NSW, Australia
   Stanford Medical Center, Palo Alto, CA, USA
   University of California - San Francisco Medical Center, USA

4. T.R. Brazelton, R.L. Doyle, C. Poirier, R.L. Wong, R.D. Newmark, T. Lin, B.A. Reitz, J. Theodore, R.E. Morris. Risks for BOS1 and Obliterative Bronchiolitis: Multivarariate Regression Analysis of 826 Transplants. 118 pages. February, 1998.

COMMISSIONED REPORTS (continued)

5. T.R. Brazelton, C. Bush, J. Hagenkord, R. Kupaswami, K. Kudsman, R.D. Newmark, R.L. Wong, R.E. Morris. Recomendations to modify inclusion and exclusion criteria for de novo studies in lung transplant recipients: A means to improve both enrollment and outcomes. March, 1998.

6. T.R. Brazelton, R.D. Newmark, R.L. Wong, R.E. Morris. Differential risk of acute rejection events during different periods post transplant. 97 pages. March, 1998.

7. T.R. Brazelton, C. Bush, R.L. Wong, R.E. Morris. Implications of various enrollment and exclusion criteriae for clinical lung transplant trials designed to test the ability of novel therapies to prevent chronic rejection utilizing existing patient pools. Results of computerized modeling with data from the *International Lung Transplant Database.* Part 1 36 pages. April, 1998.

8. T.R. Brazelton C. Bush, R.L. Wong, R.E. Morris. Implications of various enrollment and exclusion criteriae for clinical lung transplant trials designed to test the ability of novel therapies to prevent chronic rejection utilizing existing patient pools. Results of computerized modeling with data from the *International Lung Transplant Database.* Part 2. 30 pages. June, 1998.

9. T.R. Brazelton, J. Hagenkord, R. Kupaswami, C. Bush. Effects of using FEV1 as an primary outcome to monitor progression of chronic lung rejection: Computerized modeling with 826 lung transplant recipients. June, 1998.

10. T.R. Brazelton, R.E. Morris. Multivariate Risks for Survival in 826 Lung Transplant Recipients. 138 pages. July, 1998.

11. T.R. Brazelton Natural history of Bronchiolitis obliterans syndrome. 38 pages. October, 1998.

12. T.R. Brazelton Natural histories of acute rejection, graft loss, and death: Implications and recommendations for the design of drug efficacy trials with *de novo* enrollment. 57 pages. November, 1998.

13. T.R. Brazelton, C. Bush. Comparison of final proposed enrollment groups for RADB 159. 5 pages. December, 1998.

14. T.R. Brazelton Natural history of the recovery of pulmonary function following lung transplantation: Baseline predictions for clinical trials. 72 pages. December, 1998.

15. T.R. Brazelton Factors associated with increased incidences of acute rejection, graft loss, or death by post-transplant period: Implications for multicenter clinical trials in lung transplantation. 21 pages. January, 1999.

16. T.R. Brazelton Factors affecting the rate and/or magnitude of pulmonary function recovery following lung transplantation. 18 pages. January, 1999.

17. T.R. Brazelton Incidence of infectious and malignant complications following lung transplantation and associated risk factors. 14 pages. January, 1999.

ORAL PRESENTATIONS

1996 13th Annual Stanford Medical School Research Symposium, Stanford, CA

1996 8th International Conference of the Inflammation Research Association, Hershey, PA.

1996 XVI International Congress of the Transplantation Society, Barcelona, Spain.

1996 4th International Workshop on the mode of action of leflunomide, Eltville, Rhein, Germany.

1996 2nd International Congress on Lung Transplantation, Paris.

ORAL PRESENTATIONS (continued)

1996 Sixth International Alexis Carrel Conference on Graft Atherosclerosis and Chronic Rejection, Banff, Alberta, 1996 (2 presentations).

1997 17th Annual Meeting of the International Society for Heart and Lung Transplantation, London (3 presentations)

1997 3rd Loma Linda International Conference on Pediatric Heart and Lung Transplantation, Rancho Mirage, CA.

1977 Western Section of American Federation for Clinical Research, Carmel, CA.

1977 16th Annual Meeting of the American Society of Transplant Physicians, Chicago (3 presentations).

1997 14th Annual Stanford Medical School Research Symposium, Stanford, CA.

1997 Keynote speaker, Novartis Workshop on Clinical Lung Transplantation, Basel, Switzerland.

1998 Annual Meeting of the International Society for Heart and Lung Transplantation, Chicago (3 presentations).

1998 Keynote speaker, International Lung Transplant Study Group Annual Meeting, Chicago.

1998 RAD159 Investigator Meeting, Chicago.

1998 American Thoracic Society, Chicago.

1998 17th Annual Meeting of the American Society of Transplant Physicians, Chicago, IL

1998 Western Section of American Federation for Clinical Research, Carmel, CA

1998 XVII International Congress of the Transplantation Society, Montreal.

1998 9th International Conference of the Inflammation Research Association, Hershey, PA

1999 19th Annual Meeting of the International Society for Heart and Lung Transplantation, San Francisco, 1999 (3 presentations)

2000 20th Annual Meeting of the International Society for Heart and Lung Transplantation, Osaka, Japan (2 presentations)

2001 Seventh Basic Sciences Symposium of the Transplantation Society, Thun Switzerland

2002 Invited plenary talk, European Society of Cardiology, Berlin

2002 Invited plenary talk, Stem Cells & Regenerative Medicine Conference, San Diego

2002 Invited plenary talk, 2nd Annual Conference on Mesenchymal and Nonhematopoietic Stem Cells, New Orleans

2003 Invited plenary talk, American Society for Blood and Marrow Transplantation and the International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry Tandem BMT Meeting, Keystone, CO

2003 Invited talk, American Association of Blood Banks, San Diego, CA

2003 Invited plenary talk, 3rd Annual Conference on Mesenchymal and Nonhematopoietic Stem Cells, New Orleans

ACADEMIC SERVICE

1994-present Reviewer for *Cell, Circulation, Circulation Research, Current Opinion in Immunology, Development, Development and Disease, Developmental Cell, The Journal of Regenerative Medicine, EMBO, Experimental Hematology, Graft, Journal of Cell Biology, Journal of Clinical Investigation, Journal of Experimental Medicine, Journal of Heart and Lung Transplantation, Nature, NEJM, Science,* and *Transplantation*

1998 LCME re-accreditation subcommittee on basic science departments

1995-1999 Student representative, Medical admissions committee

1995-1998 Medical student rep. on Graduate Committee on Student Health

1995-1997 Director of Grants and Funding, Arbor Free Medical Clinic, Palo Alto, CA

1994-1996 American Medical Association Medical Student Rep., Stanford

Exhibit BB

FIGURES ACCOMPANYING DECLARATION UNDER 35 U.S.C. §1.132

Application No. 09/993,045, filed 13-Nov-2001
Inventor: Brazelton et al.
Title: Methods for Treating Disorders of Neuronal Deficiency with Bone Marrow Derived Cells

Examiner: Q. Janice Li
Art Unit: 1632

Figure 1: Bone marrow transplant following MPTP treatment promotes recovery of motor function in the rotorod test.

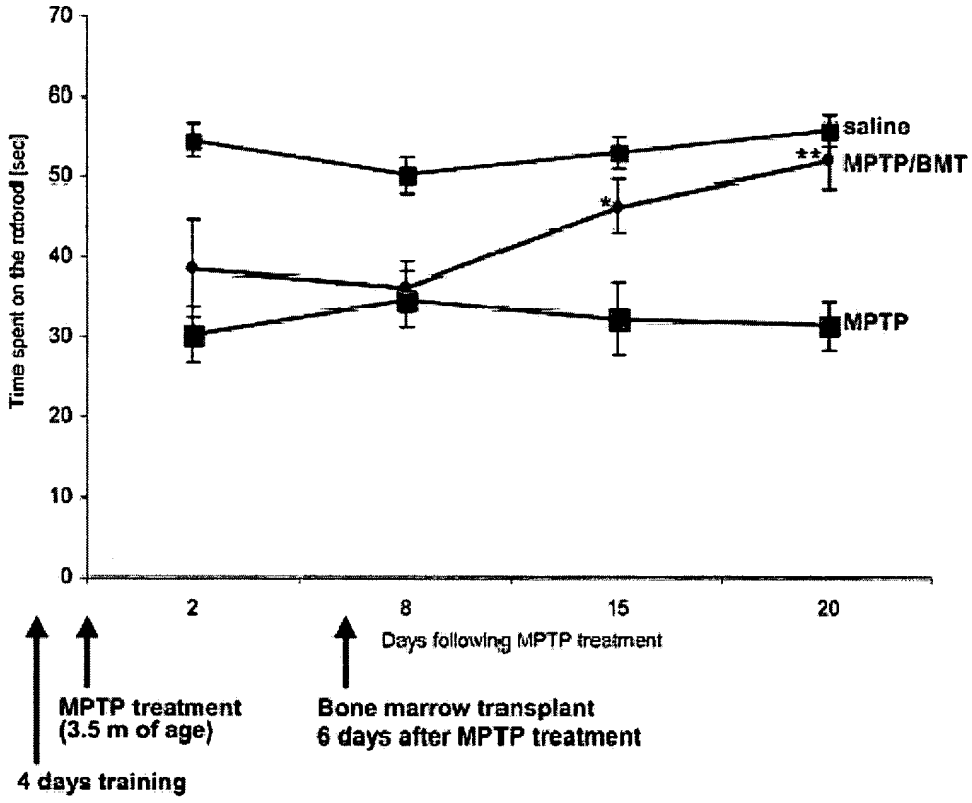

Figure 2: Bone marrow transplant before MPTP treatment promotes recovery of motor function in the rotorod test.